K072900
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510(k) Summary

APPLICANT
Hemostasis, LLC Corporation
5000 Township Parkway, St. Paul, MN 55110
Telephone: 651-855-1466
Fax: 651-651-855-1465
Contact: Keith Roberts
Title: Technical Business Development

OCT 26 2007

Company Name: Hemostasis, LLC

Classification Name: Dressing, Unclassified, Product Code – FRO

Common/Usual Name: Topical hemostatic foam

Proprietary Name: ExcelArrest™ (Rx) and (OTC) foam.

Establishment Registration Number and Manufacturing Location: To be Assigned
Hemostasis, LLC is located at 5000 Township Parkway, St. Paul, MN 55110.

Performance Standards: N/A

Substantial Equivalence: The Hemostasis, LLC ExcelArrest™ foam hemostat is Substantially Equivalent to the Hemostasis, LLC products that were the subject of premarket notification K070211, the Hemcon bandage which was subject of premarket notification K0303946 and the Vascular Solutions bandage which was subject of premarket notification K050511.

DESCRIPTION
As described above, the Hemostasis, LLC hemostats are comprised of modified chitin particles and polysaccharide binders. The particles are dissolved in water, poured into appropriate trays and using a lyophylization process, the water is removed to form a foam bandage. Chitin has well known hemostasis properties and when combined with the sodium carboxymethylcellulose and hydroxyethylcellulose binders, has an affinity to hold water. The Hemostasis foam quickly dehydrates blood cells, thereby causing rapid hemoconcentration of platelets, serum proteins and fibrinogen, leading to clotting that limits and controls bleeding in moderate to severe lacerations.

INDICATIONS FOR USE

The Hemostasis, LLC wound dressings are intended for use as topical dressings for the management of bleeding wounds.

Prescription: ExcelArrest™ is indicated for use as a topical dressing for the temporary treatment of moderate to severely bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access and percutaneous catheter access sites.

OTC: ExcelArrest™ foam is indicated for use as a topical dressing on minor bleeding wounds such as cuts, lacerations and abrasions and for minor nose bleeds.

PREDICATE DEVICES
Hemostasis, LLC bandages subject of premarket notification K070211, the Hemcon bandage which was subject of premarket notification K0303946 and the Vascular Solutions bandage which was subject of premarket notification K050511.

BIOCOMPATIBILITY
The classification and applicable testing of the Hemostasis device was determined using guidelines of ISO 10993 – Biological Evaluation of Medical Devices and FDA guidance document Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1). The criteria have been satisfied for biocompatibility.

PORCINE MODEL FOR PERFORMANCE TESTING
Comparative testing was performed using a Porcine Model and the devices met the performance criteria.

The Hemostasis, LLC products will be provided sterile.

CONCLUSION
Through the data and information presented, Hemostasis, LLC considers the devices substantially equivalent to legally marketed predicated devices cited in this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hemostasis, LLC Corporation
% Mr. Keith Roberts
Technical Business Development
5000 Township Parkway
St. Paul, MN 55110

OCT 26 2007

Re: K072900
Trade/Device Name: ExcelArrest™ Foam Hemostat Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 6, 2007
Received: November 11, 2007

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use/ Indications for Use

510(k) Number (if known):

Device Name: Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Resto
and Neurological Devices

510(k) Number k072900